Table of Contents

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2024**
**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from_____to _____**
**Commission File No. 001-35890**

# Tempest Therapeutics, Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **45-1472564** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **2000 Sierra Point Parkway, Suite 400** | |
| **Brisbane, California** | **94005** |
| (Address of Principal Executive Offices) | (Zip Code) |

**Registrant's telephone number, including area code: (415) 798-8589**

**(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)**

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, $0.001 par value | TPST | The Nasdaq Stock Market LLC |
| Series A Junior Participating Preferred Purchase Rights | N/A | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| Emerging growth company | ☐ | | |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
The number of shares of Registrant's Common Stock, $0.001 par value per share, outstanding as of November 8, 2024 was 43,642,072.

**INDEX TO FORM 10-Q**

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (the "Securities Act")) about us and our industry that involve substantial risks and uncertainties. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of our management, as well as assumptions made by, and information currently available to, our management. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "could," "expect," "anticipate," "plan," "likely," "believe," "estimate," "intend," and other similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: our strategies, prospects, plans, expectations or objectives for future operations; the progress, scope or timing of the development of our product candidates; the benefits that may be derived from any future products or the commercial or market opportunity with respect to any of our future products; our ability to protect our intellectual property rights; our anticipated operations, financial position, ability to raise capital to fund operations, revenues, costs or expenses; statements regarding future economic conditions or performance; statements of belief and any statement of assumptions underlying any of the foregoing. These risks and uncertainties include, but are not limited to, the risks included in this Quarterly Report on Form 10-Q under Part II, Item 1A, "Risk Factors." Other sections of this Quarterly Report on Form 10-Q, as well as our other disclosures and filings, include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ from those contained in, or implied by, any forward-looking statements.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this document. You should read this document with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we do not undertake any obligation to update or revise any forward-looking statements contained in this report, whether as a result of new information, future events or otherwise.

Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our expected future growth and our ability to manage such growth;
- our ability to develop, obtain regulatory approval for and commercialize amezalpat (previously known as TPST-1120), TPST-1495 and any future product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our ability to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates;
- our ability to retain regulatory approval for our product candidates or future product candidates in the United States and in any foreign countries in which we make seek to do business;
- our ability to retain and hire our board of directors, senior management, or operational personnel;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;
- our ability to remain in compliance with our obligations under our term loan with Oxford Finance LLC, or to obtain a waiver from Oxford for any failure to comply with the covenants contained in such term loan agreement;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of bank failures, public health crises or geopolitical tensions;

- our expectation regarding the period during which we will qualify as a smaller reporting company under the federal securities laws; and
- our expectations regarding our ability to obtain, maintain and enforce intellectual property protection for our products and technology, as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

You should read this Quarterly Report on Form 10-Q as well as the documents that we reference in, and have filed as exhibits to, this report with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Unless the context suggests otherwise, references in this Quarterly Report on Form 10-Q to “Tempest,” “the Company,” “we,” “us,” and “our” refer to Tempest Therapeutics, Inc. and, where appropriate, its subsidiaries.

**PART I – FINANCIAL INFORMATION**
**Item 1 – Financial Statements**
**TEMPEST THERAPEUTICS, INC.**
**Condensed Consolidated Balance Sheets**
**(in thousands, except share and per share amounts)**

| | September 30, 2024 (Unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 22,116 | $ 39,230 |
| Prepaid expenses and other current assets | 1,436 | 1,133 |
| Total current assets | 23,552 | 40,363 |
| Property and equipment — net | 932 | 840 |
| Operating lease right-of-use assets | 8,904 | 9,952 |
| Other noncurrent assets | 448 | 448 |
| Total assets | $ 33,836 | $ 51,603 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,697 | $ 845 |
| Accrued expenses | 1,459 | 1,673 |
| Current loan payable (net of discount and issuance costs of $122 and $112, respectively) | 8,504 | 4,285 |
| Current operating lease liabilities | 828 | 952 |
| Accrued compensation | 1,402 | 1,543 |
| Interest payable | 83 | 113 |
| Total current liabilities | 13,973 | 9,411 |
| Loan payable (net of discount and issuance costs of nil and $164, respectively) | — | 6,264 |
| Operating lease liabilities, less current portion | 8,406 | 9,160 |
| Total liabilities | 22,379 | 24,835 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 100,000,000 shares authorized; 26,565,886 and 22,045,255 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively | 27 | 22 |
| Additional paid-in capital | 204,723 | 192,009 |
| Accumulated deficit | (193,293) | (165,263) |
| Total stockholders' equity | 11,457 | 26,768 |
| Total liabilities and stockholders' equity | $ 33,836 | $ 51,603 |

See accompanying Notes to the Condensed Consolidated Financial Statements

**TEMPEST THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Operations**
**(Unaudited)**
**(in thousands, except share and per share amounts)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Operating expenses:** | | | | |
| Research and development | $ 7,557 | $ 4,221 | $ 17,734 | $ 13,315 |
| General and administrative | 2,994 | 2,371 | 10,374 | 8,328 |
| Loss from operations | (10,551) | (6,592) | (28,108) | (21,643) |
| **Other income (expense), net:** | | | | |
| Interest expense | (329) | (373) | (1,069) | (1,072) |
| Interest income and other income (expense), net | 324 | 179 | 1,147 | 712 |
| Total other income (expense), net | (5) | (194) | 78 | (360) |
| Provision for income taxes | — | — | — | — |
| Net loss | $ (10,556) | $ (6,786) | $ (28,030) | $ (22,003) |
| Net loss per share of common stock, RSUs and pre-funded warrants, basic and diluted | $ (0.41) | $ (0.48) | $ (1.19) | $ (1.57) |
| Weighted-average shares of common stock, RSUs and pre-funded warrants outstanding, basic and diluted | 25,806,825 | 14,121,805 | 23,537,453 | 14,059,008 |

See accompanying Notes to the Condensed Consolidated Financial Statements

**TEMPEST THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Stockholders' Equity**
**(Unaudited)**
**(in thousands, except share amounts)**

**Nine Months Ended September 30, 2024**

| | Common Stock | | Additional Paid-In | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| BALANCE — December 31, 2023 | 22,045,255 | $ 22 | $ 192,009 | $ (165,263) | $ 26,768 |
| Issuance of common stock in connection with at-the-market offering (net of issuance costs of $8) | 56,288 | — | 253 | — | 253 |
| Stock-based compensation | — | — | 1,318 | — | 1,318 |
| Issuance of common stock under equity plan awards | 115,722 | — | 197 | — | 197 |
| Net loss | — | — | — | (7,904) | (7,904) |
| BALANCE — March 31, 2024 | 22,217,265 | $ 22 | $ 193,777 | $ (173,167) | $ 20,632 |
| Issuance of common stock in connection with at-the-market offering (net of issuance costs of $261) | 2,133,534 | 2 | 4,555 | — | 4,557 |
| Stock-based compensation | — | — | 1,320 | — | 1,320 |
| Issuance of common stock under equity plan awards | 125,000 | — | — | — | — |
| Net loss | — | — | — | (9,570) | (9,570) |
| BALANCE — June 30, 2024 | 24,475,799 | $ 24 | $ 199,652 | $ (182,737) | $ 16,939 |
| Issuance of common stock in connection with at-the-market offering (net of issuance costs of $112) | 2,030,633 | 2 | 3,627 | — | 3,629 |
| Stock-based compensation | — | — | 1,334 | — | 1,334 |
| Issuance of common stock under equity plan awards | 59,454 | 1 | 110 | — | 111 |
| Net loss | — | — | — | (10,556) | (10,556) |
| BALANCE — September 30, 2024 | 26,565,886 | $ 27 | $ 204,723 | $ (193,293) | $ 11,457 |

**Nine Months Ended September 30, 2023**

| | Common Stock | | Additional Paid-In | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| BALANCE — December 31, 2022 | 10,518,539 | $ 11 | $ 153,872 | $ (135,772) | $ 18,111 |
| Issuance of common stock for cash | 43,161 | — | 44 | — | 44 |
| Stock-based compensation | — | — | 446 | — | 446 |
| Net loss | — | — | — | (7,636) | (7,636) |
| BALANCE — March 31, 2023 | 10,561,700 | $ 11 | $ 154,362 | $ (143,408) | $ 10,965 |
| Issuance of common stock for cash (net of issuance cost of $30) | 537,546 | 1 | 1,185 | — | 1,186 |
| Exercise of pre-funded warrants | 1,484,174 | 1 | — | — | 1 |
| Stock-based compensation | — | — | 440 | — | 440 |
| Exercise of stock options | 413 | — | 1 | — | 1 |
| Net loss | — | — | — | (7,581) | (7,581) |
| BALANCE — June 30, 2023 | 12,583,833 | $ 13 | $ 155,988 | $ (150,989) | $ 5,012 |
| Issuance of common stock for cash | 20,961 | — | 20 | — | 20 |
| Exercise of pre-funded warrants | 1,718,611 | 1 | — | — | 1 |
| Share-based compensation | — | — | 563 | — | 563 |
| Net loss | — | — | — | (6,786) | (6,786) |
| BALANCE — September 30, 2023 | 14,323,405 | $ 14 | $ 156,571 | $ (157,775) | $ (1,190) |

See accompanying Notes to the Condensed Consolidated Financial Statements.

**TEMPEST THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Cash Flows**
**(Unaudited)**
**(in thousands)**

| | For the Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Operating activities:** | | |
| Net loss | $ (28,030) | $ (22,003) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 340 | 296 |
| Stock-based compensation expense | 3,972 | 1,449 |
| Non-cash lease expense | 1,048 | 1,268 |
| Non-cash interest and other expense, net | 154 | 142 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 49 | 152 |
| Accounts payable | 852 | 28 |
| Accrued expenses and other liabilities | (355) | (1,281) |
| Interest payable | (30) | 9 |
| Operating lease liabilities | (878) | (1,242) |
| Cash used in operating activities | (22,878) | (21,182) |
| **Investing activities:** | | |
| Purchase of property and equipment | (432) | (163) |
| Cash used in investing activities | (432) | (163) |
| **Financing activities:** | | |
| Proceeds from the issuance of common stock in connection with at-the-market offering, net of issuance costs | 8,439 | 1,253 |
| Repayment of loan | (2,199) | — |
| Proceeds from the issuance of common stock under equity plan awards | 308 | — |
| Cash provided by financing activities | 6,548 | 1,253 |
| Net decrease in cash, cash equivalents and restricted cash | (16,762) | (20,092) |
| Cash, cash equivalents and restricted cash at beginning of period | 39,673 | 31,598 |
| Cash, cash equivalents and restricted cash at end of period | $ 22,911 | $ 11,506 |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for interest | $ 954 | $ 927 |
| Cash paid for business taxes | $ 21 | $ 152 |
| Property and equipment in accounts payable | $ — | $ 3 |

See accompanying Notes to the Condensed Consolidated Financial Statements

**TEMPEST THERAPEUTICS, INC.**

**Notes to the Condensed Consolidated Financial Statements**
**(Unaudited)**
**(Amounts are in thousands, except share and per share data)**

## 1. ORGANIZATION AND DESCRIPTION OF THE BUSINESS

***Description of Business***

Tempest Therapeutics, Inc. ("Tempest" or the "Company") is a clinical-stage biotechnology company moving into late-stage development with a diverse portfolio of targeted and immune-mediated product candidates with the potential to be first-in-class treatments for a wide range of cancers. Tempest's novel programs range from early research to the lead program, amezalpat (previously known as TPST-1120), that is poised to begin a pivotal study in first-line liver cancer. Tempest is also developing other potential product candidates in its Discovery Research group. The Company is headquartered in Brisbane, California.

***Liquidity and Management Plans***

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has incurred operating losses since inception. As of September 30, 2024, the Company had cash and cash equivalents of $22.1 million. The Company has not yet generated product sales and as a result has experienced operating losses since inception. The Company expects to incur additional losses in the future to conduct research and development and will need to raise additional capital to continue operations. The Company intends to raise such capital through the issuance of additional debt or equity including in connection with potential merger opportunities, or through business development activities. The Company's ability to continue as a going concern is dependent upon its ability to control its variable spend over the next 12 months, while management plans to secure sources of financing and ultimately attain profitable operations. If the Company are unable to obtain adequate capital, it could be forced to cease operations. Management believes that its existing cash and cash equivalents will be sufficient to fund the Company's cash requirements for at least 12 months following the issuance of these financial statements.

**ATM Program**

On July 23, 2021, the Company entered into a sales agreement with Jefferies LLC ("Jefferies"), pursuant to which the Company may sell, from time to time at its sole discretion through Jefferies, as its sales agent, shares of its common stock having, up to an aggregate sales price of $100.0 million of its common stock through Jefferies (the "Prior ATM Program"). As of June 20, 2024, the Company had sold an aggregate 9,017,110 shares of its common stock for gross proceeds of approximately $42.7 million ($41.5 million net of commissions and estimated expenses) under the Prior ATM Program. On June 20, 2024, the Company and Jefferies terminated the Prior ATM Program and entered a new Open Market Sale Agreement℠ (the "Sales Agreement") to sell shares of common stock from time to time through Jefferies acting as sales agent (the "ATM Program"). Pursuant to the prospectus supplement dated June 20, 2024 (the "Prospectus Supplement") filed by the Company with the U.S. Securities and Exchange Commission ("SEC"), the Company will be able to offer and sell up to $205,000,000 of its shares of common stock pursuant to the Sales Agreement. The Company will pay Jefferies a commission up to 3.0% of the gross sales proceeds of any shares of its common stock sold through Jefferies under the ATM Program and also has provided Jefferies with indemnification and contribution rights. As of September 30, 2024, the Company has sold an aggregate of 4,164,167 shares of its common stock for gross proceeds of approximately $8.6 million, or $8.3 million after deducting commissions and offering expenses, pursuant to the ATM Program. As of September 30, 2024, approximately $196.4 million remained available for sale under the ATM Program. Between October 1, 2024 and November 8, 2024, the Company sold 17,076,186 shares of the Company's common stock for gross proceeds of $20.5 million, or $19.9 million after deducting commissions and estimated offering expenses, pursuant to the ATM Program.

**PIPE Financing**

On April 29, 2022, the Company completed a private investment in public equity ("PIPE") financing from the sale of 3,149,912 shares of its common stock at a price per share of $2.36 and, and in lieu of shares of common stock, pre-funded warrants to purchase up to 3,206,020 shares of its common stock at a price per pre-funded warrant of $2.359 to EcoR1 Capital, LLC and Versant Venture Capital (the "PIPE Investors"). Net proceeds from the PIPE financings totaled approximately $14.5 million, after deducting offering expenses. The Company entered into a registration rights agreement with the PIPE Investors pursuant to which the Company filed a registration statement with the SEC registering the resale of the 3,149,912 shares common stock and the 3,206,020 shares of common stock underlying the pre-funded warrants issued in the PIPE financing. As of September 30, 2024, all pre-funded warrants had been exercised.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

**Significant Accounting Policies**—The Company's significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies," in the Company's Annual Report on Form 10-K filed with the SEC on March 19, 2024. There have been no material changes to the significant accounting policies during the period ended September 30, 2024.

**Basis of Presentation**—The unaudited interim Condensed Consolidated Financial Statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the United States ("GAAP") have been omitted. These unaudited interim Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements and notes included in the company's Annual Report on Form 10-K for the year ended December 31, 2023.

The Company has prepared the accompanying Condensed Consolidated Financial Statements on the same basis as the audited financial statements, and the unaudited interim financial statements include, in the Company's opinion, all adjustments, consisting only of normal recurring adjustments that the Company considers necessary for a fair presentation of its financial position and results of operations for these periods.

**Use of Estimates**—The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to research and development accruals, recoverability of long-lived assets, right-of-use assets, lease obligations, stock-based compensation and income taxes uncertainties and valuation allowances. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates.

## 3. FAIR VALUE MEASUREMENTS

The following tables present the Company's fair value hierarchy for assets measured at fair value on a recurring basis:

| | As of September 30, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents | $ 22,116 | $ — | $ — | $ 22,116 |
| Total | $ 22,116 | $ — | $ — | $ 22,116 |

| | As of December 31, 2023 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Cash and cash equivalents | $ 39,230 | $ — | $ — | $ 39,230 |
| Total | $ 39,230 | $ — | $ — | $ 39,230 |

## 4. BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets consist of the following:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Prepaid expenses | $ 811 | $ 700 |
| Prepaid research and development costs | 240 | 337 |
| Other current assets | 385 | 96 |
| Total | $ 1,436 | $ 1,133 |

Property and equipment, net, consists of the following:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Computer equipment and software | $ 192 | $ 169 |
| Furniture and fixtures | 328 | 328 |
| Lab equipment | 1,485 | 1,133 |
| Leasehold improvements | 293 | 235 |
| Property and equipment | 2,298 | 1,865 |
| Less accumulated depreciation | (1,366) | (1,025) |
| Property and equipment—net | $ 932 | $ 840 |

Depreciation expense for the three and nine months ended September 30, 2024 was $98 and $340, respectively. Depreciation expense for the three and nine months ended September 30, 2023 was $88 and $296, respectively.

Accrued liabilities consist of the following:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Accrued other liabilities | $ 1,020 | $ 626 |
| Accrued clinical trial liability | 439 | 1,047 |
| Total | $ 1,459 | $ 1,673 |

## 5. COMMITMENTS AND CONTINGENCIES

### Facilities Lease Agreements

In January 2022, the Company entered into a new 8-year office lease agreement for a 20,116 square feet facility in Brisbane, California (“Brisbane Lease”). The lease commenced in December 2022.

As of September 30, 2024 and December 31, 2023, the balance of the operating lease right of use assets were $8,904 and $9,952, respectively, and the related operating lease liability were $9,234 and $10,112, respectively, as shown in the accompanying consolidated balance sheets.

Rent expense was $486 and $1,758 for the three and nine months ended September 30, 2024, respectively. Rent expense was $685 and $2,054 for the three and nine months ended September 30, 2023, respectively.

As of September 30, 2024, future minimum lease payments under the Company's operating lease liabilities were as follows:

| Year Ending | Total Commitment |
|---|---|
| 2024 (excluding nine months ended September 30, 2024) | $ 449 |
| 2025 | 1,861 |
| 2026 | 1,926 |
| 2027 | 1,994 |
| 2028 and beyond | 6,410 |
| Total minimum lease payments | 12,640 |
| Less: imputed interest | (3,406) |
| Present value of operating lease obligations | 9,234 |
| Less: current portion | (828) |
| Noncurrent operating lease obligations | $ 8,406 |

Related to this Brisbane Lease agreement, the Company entered into a letter of credit with a bank to deposit $388 in a separate account that is classified as restricted cash to serve as security rent deposit. This amount is included in other noncurrent assets in the accompanying consolidated balance sheets as of September 30, 2024.

**6. LOAN PAYABLE**

On January 15, 2021, the Company entered into a loan agreement with Oxford Finance LLC (the “Lender”) to borrow a term loan amount of up to $35,000 to be funded in three tranches. The company has only drawn Tranche A in the amount of $15,000 which was wired to the Company on January 15, 2021. Tranche B of $10,000 expired on March 31, 2022. Tranche C of $10,000 is available at the Lender’s option.

On December 23, 2022, in connection with and following the Company’s merger with Millendo Therapeutics, Inc. (“Millendo”), the Company entered into a First Amendment to the loan agreement. The amendment modified the agreement as follows: (i) each of the Company and Millendo Therapeutics US, Inc., a Delaware corporation and wholly owned non-operating subsidiary of the Company created in connection with the merger (“Millendo US”), were joined as co-borrowers under the Loan Agreement; (ii) the interest-only repayment period was extended through December 31, 2023 (which interest-only period may be further extended through June 30, 2024 under certain circumstances); and (iii) a security interest in all of the assets of the Company and Millendo, in addition to the existing interest the Lender had in TempestTx, including any intellectual property, was granted to the Lender. In addition, the Lender permitted a one-time prepayment in the amount of $5.0 million, which the Company paid on December 23, 2022.

Following the amendment to the loan agreement, the term loan matures on August 1, 2025 and has an annual floating interest rate of 7.15% which is an Index Rate plus 7.10%. Index Rate is the greater of (i) 1-Month CME Term SOFR or (ii) 0.05%. In the fourth quarter of 2023, the Company achieved the circumstances necessary to extend the interest-only repayment period through June 30, 2024. Monthly principal payments of $733 began on July 1, 2024 and the Company paid the first principal payment to the Lender in July 2024. Related to this borrowing, the Company recorded loan discounts totaling $898 and paid $95 of debt issuance costs. These amounts would be amortized as additional interest expense over the life of the loan. As of September 30, 2024, the balance of the loan payable (net of debt issuance costs) was $8.5 million. The carrying value of the loan approximates fair value (Level 2).

For the three and nine months ended September 30, 2024, total interest expense was $329 and $1,069, respectively. For the three and nine months ended September 30, 2023, total interest expense was $373 and $1,072, respectively.

## 7. STOCKHOLDERS' EQUITY

### Common Stock

As of September 30, 2024 and December 31, 2023, the Company was authorized to issue 100,000,000 shares of common stock and 5,000,000 shares of preferred stock, each with a par value of $0.001 per share. Of the common stock shares authorized, 26,565,886 and 22,045,255 were issued and outstanding at September 30, 2024 and December 31, 2023, respectively. There were no shares subject to repurchase due to remaining vesting requirements. Common stockholders are entitled to dividends as declared by the Company's board of directors (the "Board of Directors"), subject to rights of holders of all classes of stock outstanding having priority rights as to dividends. There was no preferred stock issued nor outstanding as of September 30, 2024 and December 31, 2023.

Common stockholders are entitled to dividends as declared by the Board of Directors, subject to rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holders of each share of common stock are entitled to one vote. Except for effecting or validating certain specific actions intended to protect the preferred stockholders, the holders of common stock vote together with preferred stockholders and have the right to elect one member of the Board of Directors.

### Rights Plan

On October 10, 2023, the Board of Directors adopted a limited duration stockholder rights plan (the "Rights Plan"), effective immediately, and declared a dividend of one preferred share purchase right (each, a "Right" and collectively, the "Rights") for each outstanding share of the common stock, par value $0.001 per share (the "Common Shares"), of the Company. The dividend was effective as of October 23, 2023 (the "Record Date") with respect to stockholders of record on that date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share, (the "Preferred Shares"), of the Company at a price of $25.00 per one one-thousandth of a Preferred Share, subject to adjustment. The descriptions and terms of the Rights are set forth in a Rights Agreement, dated as of October 10, 2023 (the "Original Rights Agreement"), between the Company and Computershare Trust Company, NA. On October 9, 2024, the Company entered into Amendment No. 1 to the Original Rights Agreement (together with the Original Rights Agreement, the "Rights Agreement"). The amendment extends the expiration date until immediately following the Company's 2025 Annual Meeting of Stockholders, or, if the Company's stockholders approve the Rights Plan, on October 10, 2026, unless the Rights are earlier redeemed or exchanged by the Company. The Company does not have any obligation under the Rights Agreement to seek stockholder approval for the Rights Agreement. The Rights Agreement otherwise remains unmodified and in full force and effect in accordance with its terms.

## 8. STOCK-BASED COMPENSATION

### Equity Plans

The Board of Directors adopted the Amended and Restated 2023 Equity Incentive Plan (the "2023 Plan") on April 30, 2023, subject to approval by the Company's stockholders. On June 15, 2023, the Company's stockholders approved the 2023 Plan, which amended and restated the A&R 2019 Plan and will be a successor to, and replacement of, the A&R 2019 Plan. The number of shares of the Company's common stock reserved for issuance under the 2023 Plan will automatically increase on January 1st of each year, for a period of 10 years, from January 1, 2024 continuing through January 1, 2033, by 4% of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, or a lesser number of shares as may be determined by the Board of Directors. Accordingly, on January 1, 2024, the common stock reserved for issuance was increased by 881,810 shares. As of September 30, 2024, there were 508,017 shares available for future grant under the 2023 Plan.

The 2023 Plan allows the Company to grant stock awards to employees, directors and consultants of the Company, including incentive stock options ("ISOs"), non-qualified stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards.

The Board of Directors adopted the 2023 Inducement Plan ("2023 Inducement Plan") on June 21, 2023, pursuant to which the Company reserved 1,150,000 shares of its common stock to be used exclusively for grants of awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The 2023 Inducement Plan was approved by the Board of Directors without stockholder approval in accordance with such rule. As of September 30, 2024, there were 933,450 shares available for future grant under the 2023 Inducement Plan.

The Company measures employee and non-employee stock-based awards at grant date fair value and records compensation expense on a straight-line basis over the vesting period of the award.

**Employee Stock Ownership Plan**

The Millendo board of directors adopted the 2019 Employee Stock Purchase Plan on April 29, 2019, which became effective upon stockholder approval on June 11, 2019. On June 17, 2022, the Company's stockholders approved the Amended and Restated 2019 Employee Stock Purchase Plan (the "2019 ESPP"). The 2019 ESPP enables employees to purchase shares of the Company's common stock through offerings of rights to purchase the Company's common stock to all eligible employees.

The 2019 ESPP provides that the number of shares of common stock reserved for issuance under the 2019 ESPP will automatically increase on January 1, 2023 and continuing through (and including) January 1, 2029, by the lesser of 1.5% of the total number of shares of Common Stock outstanding on December 31st of the preceding calendar year, (ii) 500,000 shares of Common Stock, or (iii) such lesser number of shares of Common Stock as determined by the Board of Directors (which may be zero). On January 1, 2024, the common stock reserved for issuance was increased by 330,678 shares.

As of September 30, 2024, 469,337 shares of common stock remained available for future issuance under the 2019 ESPP. During the three and nine months ended September 30, 2024, 59,454 and 93,477 shares of common stock were issued under the 2019 ESPP, respectively.

**Stock Options**

Options to purchase the Company's common stock may be granted at a price not less than the fair market value in the case of both NSOs and ISOs, except for an options holder who owns more than 10% of the voting power of all classes of stock of the Company, in which case the exercise price shall be no less than 110% of the fair market value per share on the grant date. Stock options granted under the Plans generally vest over four years and expire no later than ten (10) years from the date of grant. Vested options can be exercised at any time.

The following shows the stock option activities for the nine months ended September 30, 2024 and 2023:

| | Total Options Outstanding | Weighted-Average Exercise Price |
|---|---|---|
| Balance—December 31, 2023 | 3,554,112 | $ 7.28 |
| Granted | 887,675 | 3.99 |
| Exercised | (81,699) | 1.91 |
| Cancelled and forfeited | (208,376) | 8.23 |
| Balance—September 30, 2024 | 4,151,712 | 6.64 |
| | | |
| Balance—December 31, 2022 | 1,553,041 | $ 6.66 |
| Granted | 679,150 | 1.29 |
| Exercised | (413) | 1.23 |
| Cancelled and forfeited | (50,193) | 4.36 |
| Balance—September 30, 2023 | 2,181,585 | 5.04 |

The following table summarizes information about stock options outstanding at September 30, 2024:

| | Shares | Weighted Average Remaining Contractual Life (In Years) | Weighted Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Options outstanding | 4,151,712 | 8.43 | $ 6.64 | $ 78,906 |
| Vested and expected to vest | 4,151,712 | 8.43 | $ 6.64 | $ 78,906 |
| Exercisable | 1,179,884 | 7.20 | $ 5.88 | $ 32,877 |

During the nine months ended September 30, 2024 and 2023, the Company granted employees and non-employees stock options to purchase 887,675 and 679,150 shares of common stock, respectively, with a weighted-average grant date fair value of $3.36 and $1.08 per share, respectively. As of September 30, 2024 and 2023, total unrecognized compensation costs related to unvested employee stock options were $13,648 and $2,576, respectively. These costs are expected to be recognized over a weighted-average period of approximately 2.9 years and 2.2 years, respectively.

The Company estimated the fair value of stock options using the Black-Scholes option pricing valuation model. The fair value of employee and non-employee stock options is being amortized on the straight-line basis over the requisite service period of the awards. The fair value of employee and non-employee stock options was estimated using the following assumptions for the nine months ended September 30, 2024 and 2023:

| | 2024 | 2023 |
|---|---|---|
| Expected term (in years) | 5.5 - 6.1 | 5.5 - 6.1 |
| Expected volatility | 109% - 124% | 109% - 111% |
| Risk-free interest rate | 3.5% - 4.7% | 3.4% - 3.9% |
| Dividends | — % | — % |

***Expected Term***—The expected term of options granted represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected term of the Company's employee stock options has been determined utilizing the simplified method for awards that qualify as plain-vanilla options.

***Expected Volatility***—The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Company's common stock becomes available.

***Risk-Free Interest Rate***—The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

***Dividends***—The Company has not paid any cash dividends on common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

**Stock-Based Compensation Expense**

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed consolidated statement of operations for the three and nine months ended September 30, 2024:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | $ 559 | $ 173 | $ 1,665 | $ 465 |
| General and administrative | 775 | 390 | 2,307 | 984 |
| Total | $ 1,334 | $ 563 | $ 3,972 | $ 1,449 |

**9. RETIREMENT PLAN**

The Company participates in a qualified 401(k) Plan sponsored by its professional service organization. The retirement plan is a defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. During the three and nine months ended September 30, 2024, the Company contributed $38 and $132 to the 401(k) Plan, respectively. During the three and nine months ended September 30, 2023, the Company contributed $31 and $122 to the 401(k) Plan, respectively.

**10. NET LOSS PER SHARE**

The following table sets forth the computation of the Company's basis in diluted net loss per share for the three and nine months ended September 30, 2024 and 2023 (in thousands, except share and per share amounts):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Numerator:** | | | | |
| Net loss | $ (10,556) | $ (6,786) | $ (28,030) | $ (22,003) |
| **Denominator:** | | | | |
| Weighted-average common shares outstanding | 25,806,825 | 14,121,805 | 23,537,453 | 14,059,008 |
| Weighted-average shares used in computing basic and diluted net loss per share | 25,806,825 | 14,121,805 | 23,537,453 | 14,059,008 |
| **Net loss per share attributable to common stockholders—basic and diluted** | **$ (0.41)** | **$ (0.48)** | **$ (1.19)** | **$ (1.57)** |

As of September 30, 2024 and 2023, the Company's potentially dilutive securities included unvested stock warrants and stock options, which have been excluded from the computation of diluted net loss per share attributable to common stockholders as the effect would be anti-dilutive. The issuance of pre-funded warrants and vested RSUs have been included in the computation of basic and diluted net loss per share attributable to common stockholders. Based on the amounts outstanding as of

September 30, 2024 and 2023, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

| | As of September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Options to purchase common stock | 4,151,712 | 2,181,585 |
| Restricted stock units | — | 125,000 |
| Common stock warrants | 6,036 | 6,036 |
| Total | 4,157,748 | 2,312,621 |

**Item 2.** ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

*You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited condensed financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and our audited consolidated financial statements and related notes for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission ("SEC") on March 19, 2024. This discussion and other parts of this report contains forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions, and beliefs, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors," under Part II, Item 1A of this report and those discussed in our other disclosures and filings with the SEC.*

**Overview**

We are a clinical-stage biotechnology company moving towards late-stage development with a diverse portfolio of targeted and immune-mediated product candidates with the potential to be first-in-class to treat a wide range of cancers. Our novel programs range from early research to the lead program, amezalpat (previously known as TPST-1120), that is poised to begin a pivotal study in first-line hepatocellular carcinoma ("HCC"). In addition to amezalpat, our second clinical-stage therapeutic product candidate is TPST-1495; we believe both are the first clinical-stage molecules designed to inhibit their respective targets.

Our philosophy is to build a company based upon not only good ideas and creative science, but also upon the efficient translation of those ideas into therapies that will improve patients' lives. Each of our programs are designed to provide different and independent approaches to fighting cancer, providing a portfolio of truly diversified assets.

**Amezalpat (TPST-1120) Clinical Update**

Amezalpat is a selective antagonist of peroxisome proliferator-activated receptor alpha ("PPARα"). On August 15, 2024, we announced the successful completion of our end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") regarding the development of amezalpat for the treatment first-line unresectable or metastatic HCC. The FDA provided positive feedback on the pivotal Phase 3 clinical trial design, which closely mirrors the positive randomized Phase 2 study.

The planned Phase 3 trial is designed to use the current amezalpat dose and schedule in combination with atezolizumab and bevacizumab and will be compared to atezolizumab and bevacizumab alone, the standard of care. The primary endpoint of the trial will be Overall Survival ("OS"). The FDA also agreed on a pre-specified early efficacy analysis, that if met would potentially reduce the time to primary read-out by up to 8 months.

***Randomized Phase 2 Trial Results***

As of an updated February 14, 2024 data cut, the ongoing global randomized Phase 1b/2 trial of amezalpat combined with the standard-of-care first-line regimen of atezolizumab and bevacizumab continued to show positive outcomes in patients with advanced or metastatic HCC. This study compares the amezalpat arm to the standard-of-care control and enrolled 40 patients randomized to the amezalpat arm and 30 patients randomized to the control arm. With 10 additional months of follow-up since the April 2023 primary analysis, the median OS in the amezalpat arm reached 21 months, representing a 6-month improvement over the 15-month OS in the control arm. Importantly, the hazard ratio ("HR") remained stable at 0.65 from 0.59 observed earlier, demonstrating a sustained reduction in the relative risk of death compared to the control arm.

At the cutoff date, 50% (20/40) of patients in the amezalpat arm remained in survival follow-up versus 30% (9/30) in the control arm. We believe this reinforces the meaningful clinical benefit observed in this population, with OS serving as the primary endpoint for regulatory approval globally for first-line HCC.

The confirmed objective response rate ("ORR") for the amezalpat arm remained consistent at 30%, compared to 13.3% in the control arm. Notably, one patient in the amezalpat arm who had previously achieved a partial response ("PR") as of April 2023

converted to a complete response ("CR") by February 2024, with at least an 80% reduction in tumor burden. This patient, despite having a PD-L1 score <1% and an immune desert phenotype, achieved a CR with the addition of amezalpat, highlighting its potential efficacy in hard-to-treat tumors.

Additionally, in biomarker subpopulation analyses, patients with b-catenin activating mutations (21% of the study population) showed an increased confirmed ORR of 43% and a disease control rate ("DCR") of 100% in the amezalpat arm. The triplet regimen with amezalpat remained active across PD-L1 negative tumors, with a confirmed ORR of 27% compared to a reduced ORR of 7% for the control arm.

These randomized data, combined with clinical data from the earlier Phase 1 trials that were reported at a podium presentation at the American Society of Clinical Oncology ("ASCO") annual meeting in June 2022, we believe support the advancement of amezalpat to a pivotal Phase 3 trial in first-line HCC, with further potential indications in kidney cancer ("RCC") under consideration.

***Leadership Team Expansion and Update***

In preparation for the pivotal Phase 3 of amezalpat, we continued to strengthen our leadership team. In September 2024, we announced the appointment of Sheldon Mullins as Vice President of Regulatory Affairs, following the addition of Troy Wagner as Vice President of Quality Assurance. In addition, Darrin Bomba and Henry Johnson are now serving as Vice President, Development Operations and Vice President, CMC & Medicinal Chemistry, respectively, reflecting their roles in supporting the company's late-stage clinical development.

**TPST-1495**

Our second clinical program, TPST-1495, is a dual antagonist of the EP2 and EP4 receptors of prostaglandin E2. Data from the TPST-1495 Phase 1 trial was presented at the ASCO annual meeting in June 2023, and we are planning to advance TPST-1495 in a new indication, Familial Adenomatous Polyposis ("FAP"), for which there are no approved systemic therapies. Given that prostaglandin signaling is implicated in FAP and based on positive preclinical data in a relevant mouse model, we believe there is strong mechanistic support for this approach. We are working with the Cancer Prevention Clinical Trials Network on a National Cancer Institute ("NCI")-funded Phase 2 study and subject to final approval, plan to start the study in the second half of 2024.

Beyond these clinical programs, we plan to continue to leverage our drug development and company-building experience along with academic relationships to identify promising new targets that may feed new programs into our pipeline. Our Discovery Research team employs a multidisciplinary approach to identify and validate therapeutic targets in oncology, and preclinical validation studies are then conducted to further understand the mechanism of action and potential therapeutic benefit to patients.

**Potential Future Milestones**

- Advance amezalpat into a pivotal study in first-line HCC patients where amezalpat will be studied in a combination treatment and compared to a standard-of-care therapy, subject to obtaining feedback from the FDA. We believe positive results from the ongoing randomized Phase 1b/2 study provide strategic opportunities for us. We are also evaluating further development in RCC and cholangiocarcinoma ("CCA") based on the Phase 1 data presented at ASCO 2022.

- Explore TPST-1495 beyond original tumor types of interest. We plan to complete the ongoing combination arm in patients with advanced endometrial cancer, where prostaglandin signaling is implicated, and report the data in 2024. Additionally, subject to final approval from the NCI, we are planning to advance TPST-1495 with the Cancer Prevention Clinical Trials Network into a Phase 2 study in patients with FAP in the second half of 2024.

**Recent Events**

***Roche Master Clinical Supply Agreement***

In October 2024, we entered into a master clinical supply agreement ("Roche Supply Agreement") with F. Hoffmann-La Roche Ltd. ("Roche"), pursuant to which Roche will supply Roche's atezolizumab (TECENTRIQ) for use in one or more clinical studies conducted by us involving amezalpat in combination with atezolizumab, in each case, in accordance with the applicable study protocol prepared by us and reviewed by Roche. Under the Roche Supply Agreement, the parties may execute one or more clinical supply agreement supplements (each, a "CSA Supplement") that will set forth the study to be conducted by us, the quantities of atezolizumab to be supplied by Roche for such study, and the delivery timeline for such quantities of atezolizumab.

In October 2024, we entered into a CSA Supplement for Roche to supply atezolizumab to us, free of charge, for use in our planned phase 3 trial.

***Stockholder Rights Plan***

We amended our stockholder rights plan on October 9, 2024 to extend the final expiration date until immediately following our 2025 Annual Meeting of Stockholders or, if our stockholders approve the rights plan at or prior to such meeting, to October 10, 2026, unless the rights are earlier redeemed or exchanged by the Company. We do not have any obligation under the rights plan to seek stockholder approval. The rights plan otherwise remains unmodified and in full force and effect in accordance with its original terms. The rights plan is intended to reduce the likelihood that any person or group gains control of Tempest through open market accumulation without paying stockholders an appropriate control premium or without providing the Board sufficient time to make informed judgments and take actions that are in the best interests of all stockholders.

**Going Concern**

We have no products approved for commercial sale and have not generated any revenue from product sales. From inception through September 30, 2024, we have raised $211.3 million, through sales of our capital securities.

We have never been profitable and have incurred operating losses in each period since inception. Our net losses were $28.0 million and $22.0 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $193.3 million. Substantially all of the operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for at least the next several years as we initiate and continue the clinical development of, and seek regulatory approval for, our product candidates and add personnel necessary to advance our pipeline of clinical-stage product candidates. In addition, operating as a publicly traded company involves the hiring of additional financial and other personnel, upgrading our financial information and other systems, and incurring substantial costs associated with operating as a public company. We expect our operating losses will fluctuate significantly from quarter to quarter and year to year due to timing of clinical development programs and efforts to achieve regulatory approval.

Based on our business strategy, our existing cash and cash equivalents of $22.1 million as of September 30, 2024 and the $19.9 million of net proceeds raised between October 1, 2024 and November 8, 2024 through sales of common stock under our ATM Program, will be sufficient to fund our cash requirements for at least 12 months from the date our consolidated financial statements were available to be issued. Our ability to fund continued development will require additional capital, and we intend to raise such capital through the issuance of additional debt or equity including in connection with potential merger opportunities, or through business development activities. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately attain profitable operations. If we are unable to obtain adequate capital, we could be forced to cease operations.

**Components of Results of Operations**

***Research and Development Expense***

Research and development expenses represent costs incurred to conduct research and development, such as the development of our product candidates.

We recognize all research and development costs as they are incurred. Research and development expenses consist primarily of the following:

- salaries, benefits and stock-based compensation;
- licensing costs;
- allocated occupancy;
- materials and supplies;
- contracted research and manufacturing;
- consulting arrangements; and
- other expenses incurred to advance our research and development activities.

The largest component of our operating expenses has historically been the investment in research and development activities. We expect research and development expenses will increase in the future as we advance our product candidates into and through clinical trials and pursues regulatory approvals, which will require a significant investment in costs of clinical trials, regulatory support and contract manufacturing and inventory build-up. In addition, we continue to evaluate opportunities to acquire or in-license other product candidates and technologies, which may result in higher research and development expenses due to license fee and/or milestone payments, as well as added clinical development costs.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in timely developing and achieving regulatory approval for our product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

***General and Administrative Expenses***

General and administrative expenses consist of employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation, for our personnel in executive, finance and accounting, and other administrative functions, as well as fees paid for legal, accounting and tax services, consulting fees and facilities costs not otherwise included in research and development expenses. Legal costs include general corporate legal fees and patent costs. We expect to continue to incur expenses as a result of being a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, additional insurance, investor relations and other administrative expenses and professional services.

***Other Income (Expense), Net***

Other income (expense), net consists primarily of interest expense, interest income, and various other income or expense items of a non-recurring nature.

**Results of Operations**

***Comparison of the three months ended September 30, 2024 and 2023***

The following table summarizes our operating results for the three months ended September 30, 2024 and 2023:

| | Three Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| **Operating expenses:** | | | | |
| Research and development | $ 7,557 | $ 4,221 | $ 3,336 | 79 % |
| General and administrative | 2,994 | 2,371 | 623 | 26 % |
| Loss from operations | (10,551) | (6,592) | 3,959 | 60 % |
| **Other income (expense), net:** | | | | |
| Interest expense | (329) | (373) | (44) | (12)% |
| Interest income and other income (expense), net | 324 | 179 | 145 | 81 % |
| Total other income (expense), net | (5) | (194) | 189 | 97 % |
| Provision for income taxes | — | — | — | 0 % |
| Net loss | $ (10,556) | $ (6,786) | $ 3,770 | 56 % |

*Research and development*

Our research and development expenses for the three months ended September 30, 2024 and 2023 were primarily incurred in connection with our most advanced product candidates, amezalpat and TPST-1495. We typically have various early-stage research and drug discovery projects, as well as various potential product candidates undergoing clinical trials. Our internal resources, employees and infrastructure are not directly tied to any one research and drug discovery project and our resources are typically deployed across multiple projects.

The following table shows our research and development expenses by program for the three months ended September 30, 2024 and 2023:

| | Three Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| Amezalpat | $ 3,943 | $ 727 | $ 3,216 | 442 % |
| TPST-1495 | 663 | 860 | (197) | (23)% |
| Preclinical and other | 578 | 894 | (316) | (35)% |
| Total candidate specific research costs | 5,184 | 2,481 | 2,703 | 109 % |
| Personnel and other costs | 1,725 | 1,490 | 235 | 16 % |
| Stock-based compensation and depreciation | 648 | 250 | 398 | 159 % |
| Total research and development expenses | $ 7,557 | $ 4,221 | $ 3,336 | 79 % |

Research and development expenses increased by $3.3 million to $7.6 million for the three months ended September 30, 2024, compared to three months ended September 30, 2023, which was primarily attributable to an increase in costs incurred from engaging contract research and manufacturing organizations in preparation for our pivotal Phase 3 trial of amezalpat for the

treatment of first-line HCC. The following table summarizes our research and development expenses for the three months ended September 30, 2024 and 2023:

| | Three Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| Research and development outside services | $ 4,514 | $ 2,208 | $ 2,306 | 104 % |
| Compensation expense | 1,229 | 948 | 281 | 30 % |
| Stock-based compensation expense | 559 | 173 | 386 | 223 % |
| Consulting and professional services | 653 | 207 | 446 | 215 % |
| Other expenses | 602 | 685 | (83 ) | (12 )% |
| Total research and development expense | $ 7,557 | $ 4,221 | $ 3,336 | 79 % |

*General and administrative*

General and administrative expenses increased by $0.6 million to $3.0 million for the three months ended September 30, 2024, compared to the three months ended September 30, 2023. The increase was primarily due to an increase in stock-based compensation expense due to increased headcount as well as an increase in expenses related to legal and consulting services.

*Other income (expense), net*

For the three months ended September 30, 2024 and 2023, other income (expense), net consisted of total interest expense of $329 thousand and $373 thousand, respectively, related to the loan with Oxford Finance, LLC ("Oxford" and such loan the "Oxford Loan"), and interest income of $324 thousand and $179 thousand, respectively.

***Comparison of the nine months ended September 30, 2024 and 2023***

The following table summarizes our operating results for the nine months ended September 30, 2024 and 2023:

| | Nine Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| **Operating expenses:** | | | | |
| Research and development | $ 17,734 | $ 13,315 | $ 4,419 | 33 % |
| General and administrative | 10,374 | 8,328 | 2,046 | 25 % |
| Loss from operations | (28,108 ) | (21,643 ) | 6,465 | 30 % |
| **Other income (expense), net:** | | | | |
| Interest expense | (1,069 ) | (1,072 ) | (3 ) | (0 )% |
| Interest income and other income (expense), net | 1,147 | 712 | 435 | 61 % |
| Total other income (expense), net | 78 | (360 ) | 438 | 122 % |
| Provision for income taxes | — | — | — | 0 % |
| Net loss | $ (28,030 ) | $ (22,003 ) | $ 6,027 | 27 % |

*Research and development*

Our research and development expenses for the nine months ended September 30, 2024 and 2023 were primarily incurred in connection with our most advanced product candidates, amezalpat and TPST-1495. We typically have various early-stage research and drug discovery projects, as well as various potential product candidates undergoing clinical trials. Our internal

resources, employees and infrastructure are not directly tied to any one research or drug discovery project and our resources are typically deployed across multiple projects.

| | Nine Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| Amezalpat | $ 7,022 | $ 2,080 | $ 4,942 | 238 % |
| TPST-1495 | 1,938 | 2,639 | (701 ) | (27 )% |
| Preclinical and other | 1,692 | 2,986 | (1,294 ) | (43 )% |
| Total candidate specific research costs | 10,652 | 7,705 | 2,947 | 38 % |
| Personnel and other costs | 5,116 | 4,915 | 201 | 4 % |
| Stock-based compensation and depreciation | 1,966 | 695 | 1,271 | 183 % |
| Total research and development expenses | $ 17,734 | $ 13,315 | $ 4,419 | 33 % |

Research and development expenses increased by $4.4 million to $17.7 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023, which was primarily attributable to an increase in costs incurred from engaging contract research and manufacturing organizations in preparation for our pivotal Phase 3 trial of amezalpat for the treatment of first-line HCC, as well as an increase in stock-based compensation due to increased headcount. The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and 2023:

| | Nine Months Ended September 30, | | Increase/ (Decrease) | Percentage Increase/ (Decrease) |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 vs. 2023 | 2024 vs. 2023 |
| | (in thousands, except percentages) | | | |
| Research and development outside services | $ 8,934 | $ 6,678 | $ 2,256 | 34 % |
| Compensation expense | 3,459 | 3,122 | 337 | 11 % |
| Stock-based compensation expense | 1,665 | 465 | 1,200 | 258 % |
| Consulting and professional services | 1,666 | 925 | 741 | 80 % |
| Other expenses | 2,010 | 2,125 | (115 ) | (5 )% |
| Total research and development expense | $ 17,734 | $ 13,315 | $ 4,419 | 33 % |

*General and administrative*

General and administrative expenses increased by $2.0 million to $10.4 million for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023. The increase was primarily due to an increase in stock-based compensation expense due to increased headcount as well as an increase in expenses related to legal and consulting services.

*Other income (expense), net*

For the nine months ended September 30, 2024 and 2023, other income (expense), net consisted of total interest expense of $1.1 million in each period, related to the Oxford Loan, and interest income of $1.1 million and $0.7 million, respectively.

**Liquidity and Capital Resources**

***Overview***

Since inception through September 30, 2024, our operations have been financed primarily by net cash proceeds from the sale of our common stock, convertible preferred stock and issuance of debt. As of September 30, 2024, we had $22.1 million in

cash and cash equivalents and an accumulated deficit of $193.3 million. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will continue to incur increasing losses in the foreseeable future.

We believe our cash and cash equivalents as of September 30, 2024 and the $19.9 million of net proceeds raised between October 1, 2024 and November 8, 2024 through sales of common stock under our ATM Program will fund our ongoing working capital, investing, and financing requirements into the fourth quarter of 2025.

***Loan Agreement with Oxford Finance LLC***

In January 2021, we entered into a Loan Agreement with Oxford that provided us with up to $35.0 million of borrowing capacity across three potential tranches, which was subsequently amended in December 2022. The initial tranche of $15.0 million was funded at the closing of the Loan Agreement, of which $5.0 million was repaid in December 2022. As of September 30, 2024, the balance of the loan payable (net of debt issuance costs) was $8.5 million and a total of $10.0 million in borrowing capacity remained available at the option of Oxford. Monthly principal payments of $733 thousand began on July 1, 2024 and the Company paid the first principal payment to Oxford in July 2024. The term loan matures on August 1, 2025 and has an annual floating interest rate of 7.15% which is an Index Rate plus 7.10%. Index Rate is the greater of (i) 1-Month CME Term SOFR or (ii) 0.05%. Refer to Note 6 to our consolidated financial statements for additional information on our Loan Agreement with Oxford.

***At-the-Market Offering***

On July 23, 2021, we entered into a sales agreement with Jefferies LLC ("Jefferies"), pursuant to which we may sell, from time to time at its sole discretion through Jefferies, as its sales agent, shares of its common stock having, up to an aggregate sales price of $100.0 million of its common stock through Jefferies (the "Prior ATM Program"). As of June 20, 2024, we had sold an aggregate 9,017,110 shares of its common stock for gross proceeds of approximately $42.7 million ($41.5 million net of commissions and estimated expenses) under the Prior ATM Program. On June 20, 2024, we and Jefferies terminated the Prior ATM Program and entered a new Open Market Sale Agreement℠ (the "Sales Agreement") to sell shares of common stock from time to time through Jefferies acting as sales agent (the "ATM Program"). Pursuant to the prospectus supplement dated June 20, 2024 (the "Prospectus Supplement") filed by us with the U.S. Securities and Exchange Commission ("SEC"), we will be able to offer and sell up to $205,000,000 of its shares of common stock pursuant to the Sales Agreement. We will pay Jefferies a commission up to 3.0% of the gross sales proceeds of any shares of its common stock sold through Jefferies under the ATM Program and also has provided Jefferies with indemnification and contribution rights. As of September 30, 2024, we have sold an aggregate of 4,164,167 shares of its common stock for gross proceeds of approximately $8.6 million, or $8.3 million after deducting commissions and offering expenses, pursuant to the ATM Program. As of September 30, 2024, approximately $196.4 million remained available for sale under the ATM Program. Between October 1, 2024 and November 8, 2024 the Company sold 17,076,186 shares of our common stock for gross proceeds of $20.5 million or $19.9 million after deducting commissions and estimated offering expenses, pursuant to the ATM Program.

***Cash Flows***

The following table summarizes our cash flows for the nine months ended September 30, 2024 and 2023:

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| | **(in thousands)** | |
| Cash used in operating activities | $ (22,878) | $ (21,182) |
| Cash used in investing activities | (432) | (163) |
| Cash provided by financing activities | 6,548 | 1,253 |
| Net decrease in cash and cash equivalents | $ (16,762) | $ (20,092) |

***Cash flows used in operating activities***

Cash used in operating activities for the nine months ended September 30, 2024 was $22.9 million, consisting of a net loss of $28.0 million, add back of non-cash adjustments for depreciation, stock-based compensation, non-cash operating lease expense and other non-cash items totaling $5.5 million, less changes in operating assets and liabilities of $0.4 million.

Cash used in operating activities for the nine months ended September 30, 2023 was $21.2 million, consisting of a net loss of $22.0 million, add back of non-cash adjustments for depreciation, stock-based compensation, non-cash operating lease expense and other non-cash items totaling $3.2 million, plus changes in operating assets and liabilities of $2.4 million.

***Cash flows used in investing activities***

Cash used in investing activities for the nine months ended September 30, 2024 and 2023 was related to purchases of property and equipment, primarily related to laboratory and computer equipment.

***Cash flows provided by financing activities***

Cash provided by financing activities for the nine months ended September 30, 2024 was related to proceeds from the issuance of common stock of $6.5 million.

Cash provided by financing activities for the nine months ended September 30, 2023 was related to proceeds from the issuance of common stock of $1.3 million.

***Funding Requirements***

We believe that our available cash and cash equivalents are sufficient to fund existing and planned cash requirements for the next 12 months from the date our consolidated financial statements were available to be issued. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, clinical costs, legal and other regulatory expenses and general overhead costs. We have based our estimates on assumptions that may prove to be incorrect, and we could use our capital resources sooner than we currently expect.

Our future funding requirements will depend on many factors, including the following:

- the costs associated with a pivotal study for amezalpat in first-line HCC patients, as well as other costs associated with the scope, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs associated with the manufacturing of our product candidates;
- the costs related to the extent to which we enter into partnerships or other arrangements with third parties to further develop our product candidates;
- the costs and fees associated with the discovery, acquisition or in-license of product candidates or technologies;
- our ability to establish collaborations on favorable terms, if at all;
- the costs of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

***Material Cash Requirements***

Our material cash requirements primarily relate to the maturities of the principal obligations under our long-term debt, operating leases for office space, trade payables, and accrued expenses. As of September 30, 2024, we have $14.0 million payable within 12 months, including the current loan payable (net of discount and issuance costs) of $8.5 million due to Oxford and $0.8 million related to the Brisbane Lease. Refer to Notes 5 and 6 to our consolidated financial statements for additional information. We also expect our operating expenses to continue to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Accordingly, we will need substantial additional funding in connection with our continuing operations.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs, including those set forth above, primarily through the issuance of additional equity, borrowings and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

**Critical Accounting Policies and Estimates**

There have been no significant changes to our critical accounting policies since December 31, 2023. For a description of critical accounting policies that affect our significant judgments and estimates used in the preparation of our unaudited condensed consolidated financial statements, refer to Item 7 “Management's Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K.

**Recent Accounting Pronouncements**

See Note 2 to our Condensed Consolidated Financial Statements for a description of recent accounting pronouncements applicable to our Condensed Consolidated Financial Statements.

**Smaller Reporting Company Status**

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by nonaffiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

**Item 3.** ***Quantitative and Qualitative Disclosures about Market Risk***

Not required for smaller reporting companies.

**Item 4.** ***Controls and Procedures***

**Evaluation of Disclosure Controls and Procedures**

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer (principal executive officer) and Vice-President, Strategy and Finance (principal financial officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report. Based on such evaluation, our Chief Executive Officer and Vice-President, Strategy and Finance have concluded that as of September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There were no changes in internal control over financial reporting during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

**Item 1.** ***Legal Proceedings***

Information pertaining to legal proceedings is provided in Note 5 to the Condensed Consolidated Financial Statements contained in this report and is incorporated by reference herein.

**Item 1A.** ***Risk Factors***

*Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. Any of these events could cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made or may make from time to time.*

**Summary of Selected Risks Associated with Our Business**

Our business is subject to numerous risks and uncertainties, any one of which could materially adversely affect our business, financial condition, operating results, and prospects. You should read this summary together with the more detailed description of each risk factor contained below.

- We have a history of operating losses, and we may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.
- We will need to raise additional funding to finance our operations, which may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- In the past, we have faced substantial doubt regarding our ability to continue as a going concern and may face such challenges in the future. If we are unable to maintain the cash reserves required to fund our business, we will require substantial additional funding to finance our operations, and if we are unable to raise capital, we could be forced to delay, reduce or explore other strategic options for certain of our development programs, or even terminate our operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- The terms of the Loan Agreement with Oxford Finance ("Oxford") provide Oxford with a lien against all of our assets, including our intellectual property, and contains financial covenants and other restrictions on our actions that may limit our operational flexibility or otherwise adversely affect our results of operations.
- We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- If we are unable to develop, obtain regulatory approval for and commercialize amezalpat, TPST-1495, or any of our future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

- Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, which may delay or prevent obtaining regulatory approval.
- We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.
- The commercial success of our product candidates, including TPST-1495 and amezalpat, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.
- We may rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.
- We face significant competition in an environment of rapid technological change, and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business, financial condition and ability to successfully market or commercialize TPST-1495, amezalpat, and any future product candidates.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.
- We may not be successful in finding strategic collaborators for continuing development of certain of our future product candidates or successfully commercializing or competing in the market for certain indications.
- The U.S. Food and Drug Administration ("FDA") regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.
- Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- Our owned and in-licensed patents and patent applications may not provide sufficient protection of our product candidates or result in any competitive advantage.
- The trading price of the shares of our common stock has been and is likely to continue to be volatile, and purchasers of our common stock could incur substantial losses.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.
- Our common stock is thinly traded and our stockholders may be unable to sell their shares quickly or at market price.
- If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

**Risks Related to Our Financial Position and Capital Needs**

***We have a history of operating losses, and we may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and***

***development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.***

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing, business planning, raising capital, acquiring and developing product and technology rights, manufacturing, and conducting research and development activities for our product candidates. We have never generated any revenue from product sales and we have not obtained regulatory approvals for any of our product candidates. We incurred net losses of $28.0 million and $22.0 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of $193.3 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates is approved, sales and marketing activities. Our prior losses, combined with our expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We will need to raise additional funding to finance our operations, which may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.***

Our operations have consumed significant amounts of cash since inception. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, our product candidates, including later stage clinical trials such as our potential pivotal Phase 3 trial in first-line HCC, subject to our discussions with the FDA, and advance our other programs. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Other unanticipated costs may also arise. Because the design and outcome of our ongoing and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Moreover, we will need to obtain substantial additional funding in connection with our continuing operations and planned research and clinical development activities. Our future capital requirements will depend on many factors, including:

the timing, progress, costs and results of our ongoing preclinical studies and clinical trials of our product candidates;

the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials of other product candidates that we may pursue;

- our ability to establish collaborations on favorable terms, if at all;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, reimbursement and distribution, for any of our product candidates for which we may receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we may receive marketing approval;
- the cost of any milestone and royalty payments with respect to any approved product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

We may never generate the necessary data or results required to obtain regulatory approval in order to generate revenue from product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on our cash and cash equivalents and additional financing to achieve our business objectives.

As of September 30, 2024, we had cash and cash equivalents of $22.1 million. We believe that our cash and cash equivalents as of September 30, 2024, will fund our current operating plans through at least the next 12 months from the date the financial statements were issued. We have based this assessment on assumptions that may prove to be wrong, and it is possible that we will not achieve the progress that we expect with these funds because the actual costs and timing of clinical development and regulatory and commercial activities are difficult to predict and are subject to substantial risks and delays, and that we will use our capital resources sooner than we currently expect. This estimate does not reflect any additional expenditures that may result from any further strategic transactions to expand and diversify our product pipeline, including acquisitions of assets, businesses, rights to products, product candidates or technologies or strategic alliances or collaborations that we may pursue.

Accordingly, we will require substantial additional capital to develop our product candidates. Adequate additional financing may not be available to us on acceptable terms, or at all. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we might not be able to raise funding on favorable terms, if at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions, inflation expectations, and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from public health crises and geopolitical tensions, such as the Russia-Ukraine war and the war in Israel. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or explore other strategic options for our research and development programs or other opportunities, or even our operations. If we do not obtain additional financing and are required to terminate our operations, our stockholders will lose their investment.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. In June 2024, we terminated the prior sales agreement with Jefferies LLC ("Jefferies") from July 2021 for our at-the-market program and entered into a new sales agreement with Jefferies for an at-the-market offering program (the "ATM Program"). Pursuant to the prospectus supplement we filed in June 2024, we may sell up to an aggregate of $205 million of our common stock under our ATM Program. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be further diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. In addition, we may issue equity or debt securities as consideration for obtaining rights to additional compounds.

Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming our shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could negatively impact our ability to conduct our business. For example, our obligations under the Loan Agreement with Oxford are secured by a security interest in all of our assets, including our intellectual property. In addition, the Loan Agreement contains customary covenants that, subject to specific exceptions, restrict our ability to, among other things, declare dividends or redeem or repurchase equity interests, incur additional liens, make loans and investments, incur additional indebtedness, engage in mergers, acquisitions and asset sales, transact with affiliates, undergo a change in control, add or change business locations, or engage in businesses that are not related to its existing business.

In addition, if we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

***The terms of the Loan Agreement with Oxford provide Oxford with a lien against all of our assets, including our intellectual property, and contains financial covenants and other restrictions on our actions that may limit our operational flexibility or otherwise adversely affect our results of operations.***

In January 2021, we entered into a Loan Agreement with Oxford that provided us with up to $35.0 million of borrowing capacity across three potential tranches, which was subsequently amended in December 2022. The initial tranche of $15.0 million was funded at the closing of the Loan Agreement, of which $5.0 million was repaid in December 2022. As of September 30, 2024, the balance of the loan payable (net of debt issuance costs) was $10.7 million and a total of $10.0 million in borrowing capacity remained available at the option of Oxford. Our overall leverage and certain obligations and affirmative and negative covenants contained in the related documentation could adversely affect our financial health and business and future operations by limiting our ability to, among other things, satisfy our obligations under the Loan Agreement, refinance our debt on terms acceptable to us or at all, plan for and adjust to changing business, industry and market conditions, use our available cash flow to fund future acquisitions and make dividend payments, and obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

If we default under the Loan Agreement, Oxford may accelerate all of our repayment obligations and exercise all of their rights and remedies under the Loan Agreement and applicable law, potentially requiring us to renegotiate our agreement on terms less favorable to us. In addition, since the borrowings under the Loan Agreement are secured by a lien on our assets, including our intellectual property, Oxford would be able to foreclose on our assets if we do not cure any default or pay any amounts due and payable under the Loan Agreement. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. Oxford could declare a default upon the occurrence of an event of default, including events that they interpret as a material adverse change as defined in the Loan Agreement, payment defaults or breaches of certain affirmative and negative covenants, thereby requiring us to repay the loan immediately. Any declaration by Oxford of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Additionally, if we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

Our operations to date have been limited to organizing and staffing, business planning, raising capital, acquiring our technology, identifying potential product candidates, undertaking research and preclinical studies of our product candidates, manufacturing, and establishing licensing arrangements. We have not yet demonstrated the ability to complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a licensing and research focus to a company that is also capable of supporting clinical development and commercial activities. We may not be successful in such a transition.

***Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations.***

Our ability to use our federal and state net operating losses ("NOLs") to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs.

Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. A Section 382 "ownership change" is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. We may have experienced ownership changes in the past, including as a result of the merger with Millendo, and may experience ownership changes in the future due to subsequent shifts in our stock ownership (some of which are outside of our control). Furthermore, the merger constituted an ownership change (within the meaning of Section 382 of the Code) of Millendo which may have eliminated or otherwise substantially limited our ability to use Millendo's federal and state NOLs to offset our future taxable income. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Tempest Tx, Inc. (our predecessor), Millendo's or our combined NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit our ability to use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

**Risks Related to Our Business and Strategy**

***We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, growing our capability to conduct clinical trials, and, if approved, through commercialization of our product candidates. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel, or contract with third parties to provide these capabilities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***We must attract and retain highly skilled employees to succeed.***

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan, harm our results of operations and increase our capabilities to successfully commercialize our product candidates. In particular, we believe that our future success is highly dependent upon the contributions of our senior management, particularly our Chief Executive Officer and President, Stephen Brady and our Chief Medical Officer, Sam Whiting. The loss of services of Messrs. Brady or Whiting, or any of our other senior management, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates, if approved. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse

opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

***Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.***

We may acquire additional businesses or drugs form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

**Risks Related to Our Product Development and Regulatory Approval**

***If we are unable to develop, obtain regulatory approval for and commercialize TPST-1495, amezalpat, or any of our future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.***

We plan to invest a substantial amount of our efforts and financial resources in our current lead product candidates, TPST-1495, a dual EP2/EP4 prostaglandin ("PGE2") receptor antagonist, and amezalpat, a peroxisome proliferator-activated receptor alpha ("PPARα") antagonist for the treatment of various cancers. We have initiated Phase 1 clinical trials of TPST-1495 and amezalpat for the treatment of advanced solid tumors. We anticipate receiving feedback from the FDA on our potential pivotal Phase 3 trial design for amezalpat for HCC during the third quarter of 2024. The FDA may require that we conduct additional dose optimization or Phase 2 development work prior to proceeding to a Phase 3 trial. Any delay in our ability to proceed to a pivotal trial for amezalpat will add time and expense to the development pathway and adversely impact the timing and potential for profitability. Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of TPST-1495 and amezalpat and any future product candidates, which may never occur. We currently generate no revenue from sales of any product and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require further clinical and/or preclinical development, regulatory approval in multiple jurisdictions, obtaining preclinical, clinical and commercial manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. TPST-1495 and amezalpat and any future product candidates must be authorized for marketing by the FDA, the Health Products and Food Branch of Health Canada ("HPFB"), the European Medicines Agency ("EMA"), and certain other foreign regulatory agencies before we may commercialize any of our product candidates in the United States, Canada, European Union, or other jurisdictions.

The success of TPST-1495 and amezalpat and any future product candidates depends on multiple factors, including:

- successful completion of preclinical studies, including those compliant with Good Laboratory Practice ("GLP"), or GLP toxicology studies, biodistribution studies and minimum effective dose studies in animals, and successful enrollment and completion of clinical trials compliant with current Good Clinical Practices ("GCPs");
- effective Investigational New Drug applications or other regulatory applications, that allow commencement of our planned clinical trials or future clinical trials for our product candidates in relevant territories;
- establishing and maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development of our product candidates, both in the United States and internationally;
- maintenance of arrangements with third-party contract manufacturing organizations ("CMOs") for key materials used in our manufacturing processes and to establish backup sources for clinical and large-scale commercial supply;
- positive results from our clinical programs that are supportive of safety and efficacy and provide an acceptable risk-benefit profile for our product candidates in the intended patient populations;
- receipt of regulatory approvals from applicable regulatory authorities, including those necessary for pricing and reimbursement of our product candidates;
- establishment and maintenance of patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, patient advocacy groups, third-party payors and the general medical community;

- our ability to effectively compete with developers of other therapies available in the market;
- establishment and maintenance of adequate reimbursement from third-party payors for our product candidates;
- our ability to acquire or in-license additional product candidates;
- prosecution, maintenance, enforcement and defense of intellectual property rights and claims;
- maintenance of a continued acceptable safety profile of our product candidates following approval, including meeting any post-marketing commitments or requirements imposed by or agreed to with applicable regulatory authorities;
- political factors surrounding the approval process, such as government shutdowns; or
- business interruptions resulting from geopolitical actions, including war and terrorism such as the Russia-Ukraine war and the war in Israel, natural disasters including earthquakes, typhoons, floods and fires, and public health crises.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

***Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, which may delay or prevent obtaining regulatory approval.***

Clinical development is expensive and can take many years to complete, and our outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials may not be predictive of results in later-stage clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome in later-stage or larger clinical trials, even if successful. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for their intended uses before we can seek regulatory approvals for their commercial sale. The conduct of Phase 3 trials and the submission of a New Drug Application ("NDA") is a complicated process. We have not previously completed any pivotal clinical trials, have limited experience in preparing, submitting and supporting regulatory filings, and have not previously submitted an NDA. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials and other requirements in a way that leads to NDA submission and approval of any product candidate we are developing.

Even if our clinical trials demonstrate acceptable safety and efficacy of TPST-1495 and amezalpat or any future product candidates and such product candidates receive regulatory approval, the labeling we obtain through negotiations with the FDA or foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications.

Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. In addition, different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval. If our study data does not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, including TPST-1495 and amezalpat, to the satisfaction of the FDA or foreign regulatory authorities, then the regulatory approvals for

such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with our protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until our conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. For example, the impact of public health crises or geopolitical tensions, such as the Russia-Ukraine war and the war in Israel, may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical trials, or prevent us from completing our clinical trials at all.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent unproven methods for cancer treatment, potential patients and their doctors may be inclined to use existing therapies rather than enroll patients in our clinical trials.

***Interim and preliminary data from our clinical trials that we may announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be

viewed with caution until the final data is available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

***We currently are investigating amezalpat and TPST-1495 in combination with other approved therapies, and we may in the future investigate product candidates in combination with other approved and unapproved therapies, which exposes us to additional risks.***

We are currently investigating and may continue to investigate one or more of our product candidates in combination with one or more other approved or unapproved therapies to treat cancers. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies, including shortages of those products for use in our intended clinical trials. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell our current product candidates or any product candidate we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. If the FDA or comparable foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the products we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

***Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.***

Prior to commercialization, TPST-1495, amezalpat and any future product candidates must be approved by the FDA pursuant to an NDA in the United States and pursuant to similar marketing applications by the HPFB, EMA and similar regulatory authorities outside the United States. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market TPST-1495, amezalpat or any future product candidates from regulatory authorities in any jurisdiction. We have no experience in submitting and supporting the applications necessary to gain marketing approvals, and, in the event regulatory authorities indicate that we may submit such applications, we may be unable to do so as quickly and efficiently as desired. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept or file any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Approval of TPST-1495 and amezalpat and any future product candidates may be delayed or refused for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for any of their proposed indications;
- the populations studied in clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the populations for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the facilities of third-party manufacturers with which we contract or procure certain service or raw materials, may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if our product candidates meet their pre-specified safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner and may not consider such clinical trial results sufficient to grant, or we may not be able to obtain, regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings, contraindications or Risk Evaluation and Mitigation Strategies ("REMS"). These regulatory authorities may also grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations and prospects.

***TPST-1495, amezalpat and any future product candidates may cause undesirable and/or unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.***

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. As we continue developing our product candidates and initiate clinical trials of our additional product candidates, serious adverse events ("SAEs"), undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable.

If any such adverse events occur, our clinical trials could be suspended or terminated and the FDA, the HPFB, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may adversely affect our business, financial condition, results of operations and prospects significantly, including our ability to successfully sign collaboration or license agreements with external partners. Other treatments for cancers that utilize prostaglandin E2 antagonist or a PPARα antagonist or similar mechanism of action could also generate data that could adversely affect the clinical, regulatory or commercial perception of TPST-1495 and amezalpat and any future product candidates.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh our risks, which may include, for example, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners, or other elements to assure safe use of the product.

Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings in the product labeling;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

***We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.***

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. Our business depends on our successful development and commercialization of the limited number of internal product candidates we are researching or have in preclinical development. Even if we are successful in continuing to build our pipeline, development of the potential product candidates that we identify will require substantial investment in additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply capability, building a commercial organization, and significant marketing efforts before we generate any revenue from product sales. Furthermore, such product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we cannot develop further product candidates, we may not be able to obtain product revenue in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Although our pipeline includes multiple programs, we are primarily focused on our lead product candidates, TPST-1495 and amezalpat, and we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable

commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

***Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.***

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current Good Manufacturing Practices ("cGMP"), quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed in a manner consistent with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the FFDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;

- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, it may lose any marketing approval that we have obtained, and we may not achieve or sustain profitability.

Non-compliance with Canadian and European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties.

***Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.***

To market and sell TPST-1495, amezalpat and any future product candidates in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time and data required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

**Risks Related to Commercialization and Manufacturing**

***The commercial success of our product candidates, including TPST-1495 and amezalpat, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.***

Even if the requisite approvals from the FDA, the HPFB, the EMA and other regulatory authorities internationally are obtained, the commercial success of our product candidates will depend, in part, on the acceptance of providers, patients and third-party payors of drugs designed to act as a dual antagonist of EP2 and EP4 and PPARα antagonists in general, and our product candidates in particular, as medically necessary, cost-effective and safe. In addition, we may face challenges in seeking to establish and grow sales of TPST-1495 and amezalpat or any future product candidates. Any product that we commercialize may not gain acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical

community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

***The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.***

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government payors, private health coverage insurers and other third-party payors. Even if coverage is provided, the established reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from end-stage renal disease. The Medicaid program, which varies from state-to-state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other government payors develop their coverage and reimbursement policies for drugs. One payor's determination to provide coverage for a drug product, however, does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In addition to government and private payors, professional organizations such as the American Medical Association, can influence decisions about coverage and reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit compared to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates, if approved. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls

or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by government and other third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such payors to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Recently there have been instances in which third-party payors have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product labeling. Even if we are successful in obtaining FDA approval to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

***If third parties on which we depend to conduct our planned preclinical studies or clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.***

We rely on third-party CROs, CMOs, consultants and others to design, conduct, supervise and monitor key activities relating to, testing, discovery, manufacturing, preclinical studies and clinical trials of our product candidates, and we intend to do the same for future activities relating to existing and future programs. Because we rely on third parties and does not have the ability to conduct all required testing, discovery, manufacturing, preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of discovery, manufacturing, preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs, CMOs and consultants are not our employees, and we have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties we contract with might not be diligent, careful or timely in conducting our discovery, manufacturing, preclinical studies or clinical trials, resulting in testing, discovery, manufacturing, preclinical studies or clinical trials being delayed or unsuccessful, in whole or in part.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as in accordance with GLP, GCP and other applicable laws, regulations and standards. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The FDA and other regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fails to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials have complied with GCP. In addition, our clinical trials must be conducted with product produced in accordance with cGMP. Our failure to comply with these regulations may require us to repeat clinical trials, which could delay or prevent the receipt of regulatory approvals. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

***We face significant competition in an environment of rapid technological change, and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than our therapies, which may harm our business, financial condition and our ability to successfully market or commercialize TPST-1495, amezalpat, and any future product candidates.***

The biopharmaceutical industry, and the immuno-oncology industry specifically, is characterized by intense competition and rapid innovation. We are aware of other companies focused on developing cancer therapies in various indications. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render our current or future product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities include, among other things, completing preclinical studies and initiating and completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our common stock and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue operations. A decline in the value of our common stock also could cause you to lose all or part of your investment.

***We may rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.***

We must currently rely on outside vendors to manufacture supplies and process our product candidates. We have not yet manufactured or processed our product candidates on a commercial scale and may not be able to achieve manufacturing and processing and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for any of our product candidates.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. In addition, we anticipate reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited, and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.

- Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- Contract manufacturers may not be able to execute our manufacturing procedures appropriately.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products.
- Our third-party manufacturers could breach or terminate their agreement(s) with us.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

***The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.***

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance and finished product of any product candidate for which we are responsible for preclinical or clinical development. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to regulatory approval. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The process of manufacturing drugs is complex, highly regulated and subject to multiple risks. Manufacturing drugs is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMP, the FDA may deny an NDA approval until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is in compliance. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with

cGMP. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMP.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We believe that we will rely upon a limited number of manufacturers for our product candidates, which may include single-source suppliers for the various steps of manufacture. This reliance on a limited number of manufacturers and the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.***

We currently do not have an organization for the sales, marketing and distribution of TPST-1495, amezalpat or any future product candidates, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on an alliance partner for sales and marketing. In addition, although we intend to establish a sales organization if we are able to obtain approval to market any product candidates, we may enter into strategic alliances with third parties to develop and commercialize TPST-1495, amezalpat and any future product candidates, including in markets outside of the United States or for other large markets that are beyond our resources. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

***We may not be successful in finding strategic collaborators for continuing development of certain of our future product candidates or successfully commercializing or competing in the market for certain indications.***

In the future, we may decide to collaborate with non-profit organizations, universities and pharmaceutical and biotechnology companies for the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our expense. If we elect to increase our expenditures to fund development or commercialization activities on our product candidates, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration, or any failure by our partners to perform their obligations under collaboration agreements, would adversely affect us financially and could harm our business reputation or negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates.

**Risks Related to Government Regulation**

***The FDA regulatory approval process is lengthy and time consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.***

Obtaining FDA approval is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical,

clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA may approve our product candidates for a more limited indication or a narrower patient population than originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

We may also experience delays in obtaining regulatory approvals, including but not limited to:

- obtaining regulatory authorization to begin a trial, if applicable;
- redesigning our study protocols and need to conduct additional studies as may be required by a regulator;
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of our product candidate by the FDA or other comparable foreign regulatory authorities;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, and other comparable foreign regulatory authorities;
- the availability of financial resources to commence and complete the planned trials;
- negotiating the terms of any collaboration agreements we may choose to initiate or conclude;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of third-party contractors, such as CROs, or investigators to comply with regulatory requirements, including GCPs;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards ("IRBs"), in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- inability to recruit and enroll suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- inability to add new clinical trial sites; or
- varying interpretations of the data generated from our preclinical or clinical trials;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties;

- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- inability to manufacture, or obtain from third parties, sufficient quantities of qualified materials under cGMP, for the completion in pre-clinical and clinical studies;
- problems with biopharmaceutical product candidate storage, stability and distribution resulting in global supply chain disruptions;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; or
- potential unforeseen business disruptions or market fluctuations that delay our product development or clinical trials and increase our costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts (such as the Russia-Ukraine war and the war in Israel), restrictions on trade, import or export restrictions, or public health crises.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by the Data Safety Monitoring Committee. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

***We may seek Breakthrough Therapy designation or Fast Track designation by the FDA for one or more of our product candidates but may not receive such designation. Even if we secure such designation, it may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.***

We may seek Breakthrough Therapy or Fast Track designation for some of our product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and clinical or preclinical data demonstrate the potential to address unmet medical needs for this condition, the product candidate may be eligible for Fast Track designation. The benefits of Fast Track designation include more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers, eligibility for Accelerated Approval and Priority Review, if relevant criteria are met, and rolling review, which means that a drug company can submit completed sections of our NDA for review by FDA, rather than waiting until every section of our NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the entire application has been submitted to the FDA.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA may be eligible for all features of Fast Track designation, intensive guidance on an efficient drug development program, beginning as early as Phase 1, and organizational commitment involving senior managers at FDA.

The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible, we cannot assure that the FDA would decide to grant the designation. Even if we obtain Fast Track designation and/or Breakthrough Therapy designation for one or more of our product candidates, it may not experience a faster development process, review or approval compared to non-expedited FDA review procedures. In addition, the FDA may withdraw Fast Track designation or Breakthrough Therapy designation if it believes that the designation is no longer supported. These designations do not guarantee qualification for the FDA's priority review procedures or a faster review or approval process.

***We may attempt to secure FDA approval of our product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we currently contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.***

We are developing certain product candidates for the treatment of serious conditions, and therefore may decide to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and provides a meaningful therapeutic benefit over existing treatments based upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability of or lack of alternative treatments. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's anticipated effect on irreversible morbidity or mortality or other clinical benefit. In some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the drug's predicted clinical benefit, or if other evidence demonstrates that our product candidate is not shown to be safe and effective under the conditions of use, the FDA may withdraw its approval of the drug on an expedited basis.

If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for any of our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. If any of our competitors were to receive full approval on the basis of a confirmatory trial for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would be more difficult or may not occur.

Failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate harm our competitive position in the marketplace.

***We may be unsuccessful in obtaining Orphan Drug Designation for our product candidates or transfer of designations obtained by others for future product candidates, and, even if we obtain such designation, we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.***

The FDA may designate drugs intended to treat relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for tax credits for qualified clinical research costs and exemption from prescription drug user fees. Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If a competitor is able to obtain orphan drug exclusivity prior to us for a product that constitutes the same active moiety and treats the same indications as our product candidates, we may not be able to obtain approval of our drug by the applicable regulatory authority for a significant period of time unless we are able to show that our drug is clinically superior to the approved drug. The applicable period is seven years in the United States.

We may seek Orphan Drug Designation for one or more of our product candidates in the United States as part of our business strategy. However, Orphan Drug Designation does not guarantee future orphan drug marketing exclusivity. Even after an orphan drug is approved, the FDA can also subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***Enacted and future legislation may increase the difficulty and cost for us to commercialize and obtain marketing approval of our product candidates and may affect the prices we may set.***

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act (“ACA”), was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The ACA contains provisions that may potentially affect the profitability of our product candidates, if approved, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs, and expansion of the entities eligible for discounts under the 340B Drug Pricing Program.

While Congress has not passed legislation to comprehensively repeal the ACA, legislation affecting the ACA has been signed into law, including the Tax Cuts and Jobs Act of 2017, which eliminated, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the law. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA through plan year 2025. The IRA also reduces the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. In the future, there may be other efforts to challenge, repeal or replace the ACA. It is unclear how many such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

Recently, the cost of prescription pharmaceuticals has been the subject of considerable discussion in the United States at both the federal and state levels. While several proposed reform measures will require Congress to pass legislation to become effective, Congress and the Biden administration have each indicated that it will seek new legislative and/or administrative measures to address prescription drug costs. Since the Presidential inauguration, the Biden administration has taken several executive actions that signal changes in policy from the prior administration. For example, on July 9, 2021, President Biden signed an executive order to promote competition in the U.S. economy that included several initiatives aimed prescription drugs. Among other provisions, the executive order directed the Secretary of the U.S. Department of Health and Human Services ("HHS") to issue a report to the White House that includes a plan to, among other things, reduce prices for prescription drugs, including prices paid by the federal government for such drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures and agencies are increasingly passing legislation and implementing regulations designed to control spending on and patient out-of-pocket costs for drug products. These measures include constraints on pricing, discounting and reimbursement; restrictions on certain product access and marketing; cost disclosure and transparency measures that require detailed reporting of drug pricing and marketing information both at product launch and in the event of a price increase; and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA and the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval

process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Further, changes to U.S. government priorities, policies, and/or initiatives as a result of the 2024 election cycle, could result in changes to the regulatory landscape, which could adversely impact our business, financial condition, and results of operations.

***The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions, and could greatly impact healthcare and the pharmaceutical industry.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security, and our failure to comply with them could harm our business.***

We collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical and clinical studies. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the processing of personal data, including health information privacy laws, security breach notification laws, consumer protection laws, and other similar laws (e.g., wiretapping laws). Each of these laws is subject to varying interpretations and constantly evolving. In addition, we obtain health information from third parties (including research institutions from which it obtains clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes specific requirements relating to the privacy, security, and transmission of protected health information.

Certain states have also adopted comprehensive privacy laws and regulations that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA") gives California residents expanded rights to access and delete their personal data, opt out of certain personal data sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase our compliance costs and potential liability. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, in Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and similar provincial laws may impose obligations with respect to processing personal data, including health-related information. PIPEDA requires companies to obtain an individual's consent when collecting, using or disclosing that individual's personal data. Individuals have the right to access and challenge the accuracy of their personal data held by an organization, and personal data may only be used for the purposes for which it was collected. If an organization intends to use personal data for another purpose, it must again obtain that individual's consent. Failure to comply with PIPEDA could result in significant fines and penalties.

As another example, the European Union's General Data Protection Regulation (the "EU GDPR") and the United Kingdom's GDPR (together with EU GDPR, "GDPR") also impose strict requirements for processing personal data and substantial fines for breaches and violations (for example, under the EU GDPR, up to the greater of €20 million or 4% of our annual worldwide gross revenue). Additionally, under GDPR, companies may face temporary or definitive bans on data processing and other corrective action or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Further, Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and, we may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Compliance with these obligations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms designed to ensure compliance with these obligations. If we fail (or are perceived to have failed) to comply with any such obligations, we may face significant consequences, including without limitation government enforcement actions (e.g., investigations, fines and penalties, audits, inspections); litigation (including class-action claims) and mass arbitration demands); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; imprisonment of company officials; or other consequences that could adversely affect our business, financial condition and results of operations.

***If our information technology systems or those of third parties upon which we rely, or our data, are or were compromised, we could experience adverse consequences, including disclosure of sensitive information, damage to our reputation, and significant financial and legal exposure.***

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are increasing in their frequency, sophistication and intensity, have become increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service attacks, social engineering attacks (including through deep-fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), credential stuffing attacks, credential harvesting, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data, attacks enhanced or facilitated by artificial intelligence or other information technology assets, fraud or other means to threaten confidentiality, integrity and availability of our sensitive information. We and the third parties upon which we rely may also experience telecommunications failures, natural disasters, terrorism, war and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

As more of our employees work remotely, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers.” Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, we rely on third parties and their technology to operate critical business systems to process sensitive information, including our CROs, CMOs and other contractors, consultants and law and accounting firms. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If these third parties experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party partners fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised.

Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our and the third parties’ upon which we rely hardware and software). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information. Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

A successful or perceived security incident experienced by us or the third parties upon which we rely could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of sensitive information, disclosure of corporate strategic plans, material disruption of our development programs and our business operations, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections), additional reporting requirements and/or oversight, restrictions on processing sensitive information, litigation, indemnification obligations, reputational harm, negative publicity, and other harms. For example, the loss of data from preclinical studies or clinical trials could result in significant delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in a loss of, or damage to, our sensitive information or applications, or inappropriate disclosure of such information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be significantly delayed.

***Our employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and could cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, a criminal law that prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti-Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal health care programs;

- the federal civil False Claims Act, imposes significant civil penalties and treble damages, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Criminal Statute on False Statements Relating to Health Care Matters makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the Federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to

healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, among others, to track and report payments and other transfers of value provided during the previous year to U.S. licensed physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and, teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

- Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be costly to us in terms of money, time and resources, and we may be subject to criminal, civil or administrative sanctions, including exclusion from government-funded healthcare programs.

***If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. our operations also may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Changes in tax laws or regulations could materially adversely affect us.***

New tax laws or regulations could be enacted at any time, and existing tax laws or regulations could be interpreted, modified or applied in a manner that is adverse to us, which could adversely affect our business and financial condition. For example, legislation enacted in 2017, informally titled the Tax Act, enacted many significant changes to the U.S. tax laws, including changes in corporate tax rates, the utilization of NOLs and other deferred tax assets, the deductibility of expenses, and the taxation of foreign earnings. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. The impact of changes under the Tax Act, the CARES Act, or future reform legislation could increase our future U.S. tax expense and could have a material adverse impact on our business and financial condition.

**Risks Related to Our Intellectual Property**

***Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.***

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, trade secret and other intellectual property protection of our proprietary technologies and product candidates, which include TPST-1495, amezalpat and any future product candidates we have in development, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to our, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development activities before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and may be reliant on our licensors or licensees to do so. Our pending and future patent applications may not result in issued patents. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-licenses may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

***We currently and may in the future depend on intellectual property licensed from third parties, and our current or future licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property***

***licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that may be important to our business.***

We currently license intellectual property from the Regents of the University of California and may in the future depend on patents, know-how and proprietary technology licensed from third parties. Our licenses to such patents, know-how and proprietary technology may not provide exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products in the future. The agreements under which we license patents, know-how and proprietary technology from others may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

We may in the future need to obtain licenses from third parties to advance our research or allow commercialization of product candidates Tempest may develop. It is possible that we may be unable to obtain any licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or product candidates.

If our current or future licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We may not have complete control over the maintenance, prosecution and litigation of our current or future in-licensed patents and patent applications. For example, we cannot be certain that activities such as the maintenance and prosecution by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our current or future licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the resolution of any contract interpretation disagreement that may arise could narrow what we might believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our current or future licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- royalty, milestone or other payment obligations that may result from the advancement or commercial sale of any of our product candidates; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we currently license or may license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates.

***Our owned and in-licensed patents and patent applications may not provide sufficient protection of our product candidates or result in any competitive advantage.***

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent applications are pending, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO"), or become involved in interference or derivation proceedings, or equivalent proceedings in foreign jurisdictions. Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, revocation, reexamination, post-grant and *inter partes* review proceedings. An adverse determination in any such submission, proceeding or litigation may result in loss of patent rights, loss of exclusivity, patent term adjustment being jeopardized, patent term being reduced, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Moreover, some of our owned and in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced or eliminated.

Since patent applications in the United States and other countries are confidential for a period of time after filing or until issuance, at any moment in time, we cannot be certain that it was in the past or will be in the future the first to file any patent application related to our product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court, patent office or other governmental authority to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing such claims. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to our products and technology. Those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop products that have the same effect as our product candidates on an independent basis that do not infringe

our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our product candidates or their use. Likewise, our currently owned patents and patent applications, if issued as patents, directed to our proprietary technologies and our product candidates are expected to expire from 2033 through 2045, without taking into account any possible patent term adjustments or extensions. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Additionally, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of the pending patent applications we own or in-license currently or in the future. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, results of operations and prospects.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the active compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- we, or our current or future licensors, as the case may be, may fail to meet our or our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- we, or our current or future licensors, as the case may be, might not have been the first to file patent applications for certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, as the case may be, or parts of our owned or in-licensed patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- the laws of foreign countries may not protect our, or our current or future licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not adequately cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;

- it is possible that our owned or in-licensed patents or patent applications may omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

***Our strategy of obtaining rights to key technologies through in-licenses may not be successful.***

The future growth of our business may depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either we or our third-party research partner, or jointly between us and the third party. If we determine that exclusive rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our drug candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party in order to use the improvements and continue developing, manufacturing or marketing our drug candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our drug candidates or allow our competitors or others the opportunity to access technology that is important to our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

In addition, the in-licensing and acquisition of these technologies is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business and prospects could be materially and adversely affected.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to patent protection, we rely upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information (or as otherwise permitted by applicable law), are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also adopted policies and conducts training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, such as through a security incident, or if any of that information was independently developed by a competitor, our competitive position could be harmed. Additionally, certain trade secret and proprietary information may be required to be disclosed in submissions to regulatory authorities. If such authorities do not maintain the confidential basis of such information or disclose it as part of the basis of regulatory approval, our competitive position could be adversely affected.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may result in substantial cost and require significant time from our scientists and management. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology, through legal or illegal means. As a result, we may not be able to meaningfully protect our trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Third-party claims of intellectual property infringement may prevent, delay or otherwise interfere with our product discovery and development efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued,

the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate their intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses our product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, including by enforcing our patents against us by filing a patent infringement lawsuit against us. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware of with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringe upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, or materials used in or formed during the manufacturing process, or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtain a license under the applicable patents, or until those patents were to expire or those patents are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for

manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if such patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all.

In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid.***

Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings), or we may choose to challenge a third party's patent in patent opposition proceedings in the Canadian Intellectual Property Office ("CIPO"), the European Patent Office ("EPO"), or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CIPO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business financial condition, results of operations and prospects.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, patents covering methods-of-use are not available in certain foreign countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not have or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert management's efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert management's efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to the Russia-Ukraine war may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceedings. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable laws and rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business financial condition, results of operations and prospects.

***Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the Leahy-Smith America Invents Act ("America Invents Act"), the United States moved from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes continue to evolve as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. Moreover, the America Invents Act and our implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. We cannot predict how decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the Federal Circuit recently issued a decision involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obviousness-type double patenting. This decision creates uncertainty to the patent terms of certain U.S. patents that share the same priority claim where on expires later than another due to accrued PTA. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain or license in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not patent-eligible.

Similarly, other cases by the U.S. Supreme Court have held that certain methods of treatment or diagnosis are not patent-eligible. U.S. law regarding patent-eligibility continues to evolve. While we do not believe that any of our patents will be found invalid based on these changes to U.S. patent law, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents and patent applications. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

As a further example, as of June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). In 2012, the European Union Patent Package (The "EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. As a single court system can invalidate a

European patent, we, where applicable, may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the opt-out formalities and requirements under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our financial condition, prospects and results of operations.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***If we do not obtain patent term extension for any product candidates it may develop, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. U.S. and ex-U.S. law concerning patent term extensions and foreign equivalents continue to evolve. Even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period of extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than it requests, our competitors may obtain approval of competing products following our patent expiration sooner than expected, and our business, financial condition, results of operations and prospects could be materially harmed.

***Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.***

Our patent application in-licensed from the Regents of the University of California has been supported through the use of U.S. government funding awarded by the National Institutes of Health. Although we do not currently own issued patents or pending patent applications that have been generated through the use of U.S. government funding, we may acquire in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that:

(1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as march-in rights). Recently, the government released a draft framework that may be used by an agency when deciding to exercise its march-in rights for public comments, and as such, the framework for deciding when march-in rights are exercised may change. If the U.S. government exercised its march-in rights in our current or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

**Risks Related to Ownership of Our Common Stock and Other General Matters**

***The trading price of the shares of our common stock has been and is likely to continue to be volatile, and purchasers of our common stock could incur substantial losses.***

The market price of our common stock has been and is likely to continue to be volatile. For example, during 2023, the closing price of our common stock on The Nasdaq Capital Market ranged from $0.23 per share to $9.77 per share. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;

- changes in the market valuations of similar companies;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad, including as a result of bank failures, public health crises or geopolitical tensions, such as the Russia-Ukraine war and the armed conflict in Israel and the Gaza Strip; and
- period-to-period fluctuations in our financial results.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.***

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the macroeconomic uncertainty and volatile business environment have resulted in ongoing inflation, volatility in the capital markets, significantly reduced liquidity and credit availability, decreases in consumer demand and confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Our general business strategy may be materially or adversely impacted by if these unpredictable and unstable market conditions continue. Additionally, the recent bank closures and geopolitical tensions, like the Russia-Ukraine war and the war in Israel, has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may have adverse consequences for us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of future bank closures or political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Inflation can adversely affect us by increasing our costs, including salary costs. Any significant increases in inflation and related increase in interest rates could have a material adverse effect on our business, results of operations and

financial condition. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply and clinical trial disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Our common stock is thinly traded and our stockholders may be unable to sell their shares quickly or at market price.***

Although we have had periods of high-volume daily trading in our common stock, generally our stock is thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. Our common stock price could, for example, decline significantly as a result of sales of a large number of shares of our common stock on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price, or from the perception that these sales could occur.

***We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are a "smaller reporting company" as defined in Section 12 of the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including not being required to comply with the auditor attestation requirements of Section 404 of Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

**Risks Related to Our Status as a Public Company and Other General Matters**

***We expect to continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

We continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Stock Market (Nasdaq) and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, in September 2023, we received a notice from Nasdaq notifying us that for the previous 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2). We were able to achieve compliance within the 180 calendar day compliance period, but there can be no assurance that we will remain in compliance with the requirements for listing our common stock on Nasdaq. Delisting could adversely affect our ability to raise additional capital through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common shares. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. Also, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, compared to when we were a private company, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we will continue to incur as a public company or the timing of such costs. Once we are no longer a smaller reporting company or otherwise no longer qualifies for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.***

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting and a report by management on, among other things, the effectiveness of our internal control over financial reporting. We will not be required to have our auditors formally attest to the effectiveness of our internal control over financial reporting until we cease to be a smaller reporting company.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. We cannot assure you that there will not be material weaknesses or significant deficiencies in the internal control over financial reporting in the future.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to accurately report our financial condition, results of operations or cash flows.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq Stock Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***We or the third parties upon whom we depend may be adversely affected by natural disasters and other calamities, including public health crises, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, fire, hurricane, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our suppliers' manufacturing facilities, or that otherwise disrupted operations, such as data storage, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Occurrences of epidemics or pandemics, depending on their scale, may cause different degrees of damage to the national and local economies within our geographic focus. Global economic conditions may be disrupted by widespread outbreaks of infectious or contagious diseases, and such disruption may adversely affect clinical development plans. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

***Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.***

We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under U.S. state consumer protection acts. If we cannot successfully defend against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- termination of our collaboration relationships or disputes with our collaborators;
- voluntary product recalls, withdrawals or labeling restrictions; and
- the inability to commercialize any product candidates that we may develop.

While we currently have insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to clinical development or marketing any of our future product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Provisions in our certificate of incorporation and by-laws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control of the company that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;

- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- prohibit actions by our stockholders by written consent;
- require that stockholder actions be effected at a duly called stockholders meeting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

In addition, in October 2023, we implemented a Rights Plan, also called a "poison pill," that may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to acquire us without the consent of our board of directors. We amended the Rights Plan on October 9, 2024. As a result of the amendment, the rights will expire immediately following our 2025 Annual Meeting of Stockholders, or, if our stockholders approve the Rights Plan, on October 10, 2026, unless the rights are earlier redeemed or exchanged by us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15 percent or more of our outstanding voting stock, unless the merger or combination is approved in a manner prescribed by the statute.

***Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.***

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against it arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

***We do not anticipate that we will pay any cash dividends in the foreseeable future.***

The current expectation is that we will retain our future earnings, if any, to fund our growth as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We have no control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults upon Senior Securities**

Not applicable.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

**Insider Trading Arrangements**

During our last fiscal quarter, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 6. Exhibits**

The following exhibits are incorporated by reference or filed as part of this report.

| Exhibit Number | Description of Exhibit | Incorporation by Reference | | | | Filed or Furnished Herewith |
|---|---|---|---|---|---|---|
| | | Form | File Number | Exhibit | Filing Date | |
| 3.1 | Restated Certificate of Incorporation of the Registrant, as amended | 10-Q | 001-35890 | 3.1 | 5/15/2019 | |
| 3.2 | Certificate of Amendment to the Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 24, 2021 | 8-K | 001-35890 | 3.1 | 6/28/2021 | |
| 3.3 | Certificate of Amendment to the Restated Certificate of Incorporation of the Company, as filed with the Secretary of State of the State of Delaware on June 25, 2021 | 8-K | 001-35890 | 3.2 | 6/28/2021 | |
| 3.4 | Certificate of Designation of Series A Junior Participating Preferred Stock filed with the Secretary of State of the State of Delaware on October 10, 2023 | 8-K | 001-35890 | 3.1 | 10/11/2023 | |
| 3.5 | Amended and Restated Bylaws of the Registrant | 8-K | 001-35890 | 3.1 | 9/24/2021 | |
| 4.1 | Amendment No. 1, dated as of October 9, 2024, to Rights Agreement, dated as of October 10, 2023, by and between Tempest Therapeutics, Inc. and Computershare Trust Company, N.A., as rights agent | 8-K | 001-35890 | 4.1 | 10/10/2024 | |
| 31.1 | Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32.1^ | Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002 | | | | | X |
| 101.INS | Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document) | | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents | | | | | X |
| 104 | The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, has been formatted in Inline XBRL. | | | | | |

^ These certifications are being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

** Pursuant to Item 601(b)(10)(iv) of Regulation S-K, certain portions of this exhibit (marked by [***]) have been omitted because the identified information is the type that the registrant treats as private or confidential and is not material.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TEMPEST THERAPEUTICS, INC.

By: /s/ Stephen Brady
Stephen Brady
Chief Executive Officer & President (Principal Executive Officer)

By: /s/ Nicholas Maestas
Nicholas Maestas
Vice-President, Strategy and Finance (Principal Financial Officer)

Date: November 12, 2024

**Exhibit 31.1**

**CERTIFICATIONS**

I, Stephen Brady, certify that:

1. I have reviewed this Form 10-Q of Tempest Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Stephen Brady
Stephen Brady
Chief Executive Officer & President

**Exhibit 31.2**

**CERTIFICATIONS**

I, Nicholas Maestas, certify that:

1. I have reviewed this Form 10-Q of Tempest Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

By: /s/ Nicholas Maestas
Nicholas Maestas
Vice-President, Strategy and Finance

**Exhibit 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Stephen Brady, Chief Executive Officer of Tempest Therapeutics, Inc. (the "Company"), and Nicholas Maestas, Vice President, Strategy and Finance, of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2024

| | |
|---|---|
| /s/ Stephen Brady | /s/ Nicholas Maestas |
| Stephen Brady | Nicholas Maestas |
| Chief Executive Officer & President | Vice-President, Strategy and Finance |

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tempest Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.